

AIB1 polypeptide. Group III, claim 41, is drawn to an antibody that binds specifically to the AIB1 polypeptide of claim 12. Group IV, claims 14-21 and 26-27 are drawn to methods of identifying compounds which inhibit estrogen receptor (ER)-dependent transcription by determining whether the compound binds to the AIB1 polypeptide of claim 12. Group V, claims 22-25 and 28-31, are drawn to methods of detecting aberrantly proliferating cells by determining intracellular levels of the AIB1 polypeptide of claim 12. Group VI, claims 32-40 and 53-54, are drawn to methods of reducing cancer cell proliferation by administering a compound that inhibits expression of the AIB1 polypeptide of claim 12. Group VII, claims 42-44 are drawn to a method of identifying a tamoxifen-sensitive patient by determining the level of AIB1 gene expression. Group VIII, claims 45 and 47-52 are drawn to transgenic animals wherein at least one copy of the AIB1 gene encoding the AIB1 polypeptide of claim 12 or of the pCIP gene has been functionally altered.

Applicants provisionally elect to prosecute the AIB1 polynucleotide claims of Group I, with traverse.

According to the unity of invention allegation, groups I-VIII are said not to relate to a single general inventive concept because they lack the same or corresponding special technical features. Specifically, the restriction requirement states that the inventive concept of an AIB1 gene was disclosed in Guan et al., Cancer Research 56: 3446-3450 (August 1, 1996), thereby negating a technical relationship between Groups I-VIII, and supporting a lack of unity of invention requirement.

In response, the applicants respectfully note that Guan et al. is their own work, published less than one year prior to the priority date (June 17, 1997) of the present application. Additional authors of Guan et al. (Guan, Xu, Anzick, and Zhang) did not make an inventive contribution to the subject matter of the invention as claimed. Accordingly, Guan et al. is not available as a prior art reference during United States prosecution, and may not be used to support a lack of unity of invention allegation.

As noted by the Examiner in Paper No. 11 at page 4, lines 3-6, the inventive concept of an AIB1 gene is a special technical feature which may be used to establish a technical relationship between the claimed groups, and thereby establish unity of invention. Applicants submit that Groups II-VIII share the special technical feature of the AIB1 gene, as outlined below:

The substantially purified polypeptides of Group II share the special technical feature of Group I, since these peptides are encoded by the polynucleotides of Group I.

The antibodies of Group III specifically bind to the polypeptides of Group II, which are encoded by the polynucleotides of Group I.

The claims of Group IV include methods of identifying compounds that inhibit ER-dependent transcription, and are based on the use of the AIB1 polypeptides of Group II. The polypeptides of group II are encoded by the polynucleotides of Group I.

The claims of Group V include methods of detecting aberrantly proliferating cells by determining the level of AIB1 polynucleotide expression. Since Group I includes AIB1 polynucleotides, Group V shares a special technical feature with Group I.

In Group VI, methods are described for reducing proliferation of cancer cells by inhibiting expression of the Group I AIB1 polynucleotides or of Group II polypeptides.

In Group VII, the methods of identifying a tamoxifen-sensitive patient include determining the level of expression of AIB1 polynucleotides of Group I.

The transgenic animals of group VIII include animals in which AIB1 gene expression is altered. Accordingly, the animals share the special inventive feature of Group I.

Rule 13.2, PCT regulations states in part that "the requirement of unity of invention... shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." Since Guan et al. is not prior art against the claims, Groups I-VIII share the special technical feature of the AIB1 gene, and there is a technical relationship between all groups. Accordingly, Groups I-VIII satisfy the unity of invention requirement presented in Rule 13.1, PCT Regulations. Applicants therefore believe that the lack of unity of invention requirement should be withdrawn.

If the restriction requirement is not completely withdrawn, applicant suggests that Groups I, II, and V have a particularly strong technical relationship to each other. Claims in these groups include claims to the AIB1 gene and polypeptide, and to detection of AIB1 gene expression in

aberrantly proliferating cells. Applicant believes that this grouping clearly satisfies the unity of invention requirement, and that examining these claims would not impose an undue additional burden upon the Examiner.

Reconsideration of the restriction requirement is respectfully requested. The Examiner is invited to telephone the undersigned at the telephone number listed below if any questions remain about the restriction requirement.

Respectfully submitted,

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